CHAPTER 1

INTRODUCTION

1-1. Purpose. This manual implements policy and provides guidance, procedures, and criteria for the validation of commercial and U.S. Army Corps of Engineers (USACE) division analytical chemistry laboratories. Laboratory validation is required to ensure that analytical chemistry laboratories meet the USACE Chemical Data Quality Management (CDQM) requirements as prescribed in the USACE Engineer Regulation (ER) 1110-1-263 for generation of chemical data of sufficient quality to meet intended usages within the project.

1-2. Applicability.

a. This manual applies to HQUSACE/OCE elements, major subordinate commands, districts, laboratories, and separate field operating activities (FOA) having responsibility for in-house or contracted projects involving chemical measurements of waste and/or environmental samples. This includes, but is not limited to, execution of the following programs: Defense Environmental Restoration Program (DERP); Base Realignment and Closure (BRAC); Installation Environmental Compliance; Military Construction; Superfund; Civil Works; and Department of Energy (DOE).

b. This manual and its prescribed laboratory validation process also apply to the validation of USACE division laboratories with minor modifications. USACE division laboratories and commercial laboratories, which perform the QA function, shall be evaluated under more stringent criteria than commercial primary project laboratories.

1.3 References.

a. ER 1110-1-263, Chemical Data Quality Management for Hazardous Waste Remedial Activities.

b. “Hazardous, Toxic & Radioactive Waste (HTRW) - Policy Guidance on Validation of Commercial Analytical Chemistry Laboratories”, CEMP-RT memorandum, (See Appendix A.)

1-4. Overview.

a. The purpose of laboratory validation is to ensure that analytical chemistry laboratories meet the minimum requirements of the USACE quality assurance/quality control (QA/QC) program that facilitates the generation of chemical data of known and

acceptable quality. Objectives of commercial laboratory validation are: to communicate USACE QA/QC requirements; to verify that commercial laboratories are performing specified analytical methods with no unacceptable deviations; and to verify these laboratories meet USACE QA/QC requirements prior to sample analysis. In general, all commercial laboratories that support USACE HTRW response activities shall obtain a USACE laboratory validation prior to field studies or sample analyses and shall maintain the validated status throughout the response activities. Appendix B is an introduction to laboratory validation procedures for commercial laboratories that express interest in USACE laboratory validation but have not been tasked to execute chemical analysis in support of USACE HTRW response activities.

b. The USACE laboratory validation process consists of three major sequential steps: (1) review of general qualifications, (2) analysis of performance evaluation (PE) samples, and (3) on-site laboratory inspection. The validation provides a parameter, method, and matrix-specific approval. The period of validation is 18 months. For each new contract/ project/task order (hereafter referred to as the contract or project) awarded to a commercial laboratory after its initial validation, a project-specific evaluation of the laboratory's capability and past performance is still required. A simplified flow diagram is shown in Figure 1-1 to show the major events in a laboratory validation process.

c. Abbreviations, acronyms, formulas, symbols, numbers, and terms used in this manual are defined in Appendix M.

1-5. Responsibilities. The USACE HTRW Mandatory Center of Expertise (HTRW MCX) located at the Missouri River Division in Omaha, Nebraska is tasked by HQUSACE with the operation and management responsibilities for this centralized laboratory validation program. A Laboratory Validation Committee (hereafter referred to as the Committee), composed of staff members from the Chemistry Branch of the HTRW MCX, is generally responsible for all aspects of the USACE HTRW laboratory validation program. One of the Committee members is designated as the Laboratory Validation Coordinator (hereafter referred to as the Coordinator) who is the point-of-contact for the Committee and is responsible for coordination and execution of the daily activities of the laboratory validation process. The Committee will meet as needed and is primarily responsible for proposing policy and making ultimate decisions with regard to laboratory-specific validation status. Besides the Committee, a number of other parties, including government agencies and private contractors, are involved in the USACE HTRW laboratory validation process.

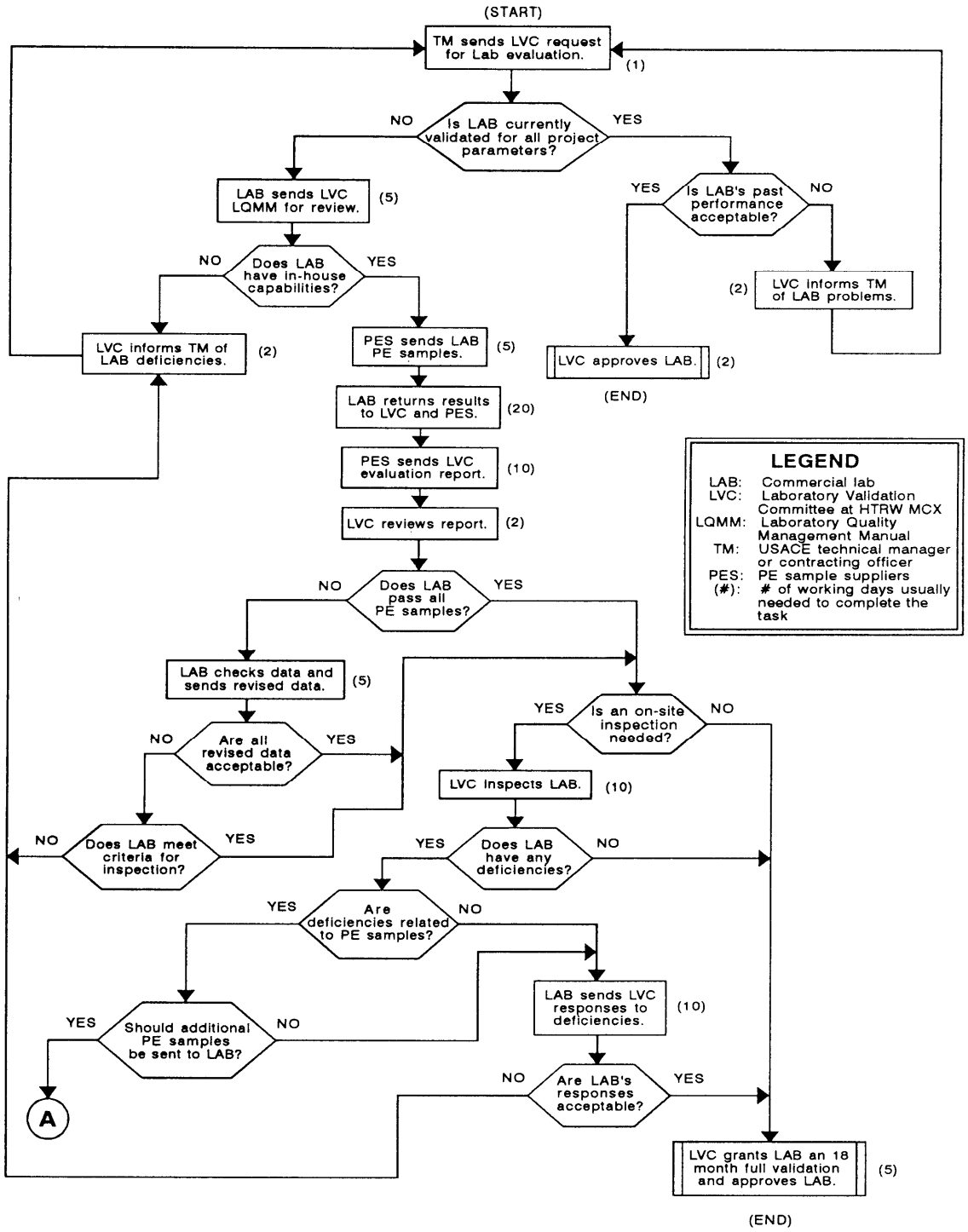

Figure 1-1. Flow Diagram of Commercial Laboratory Validation Procedures

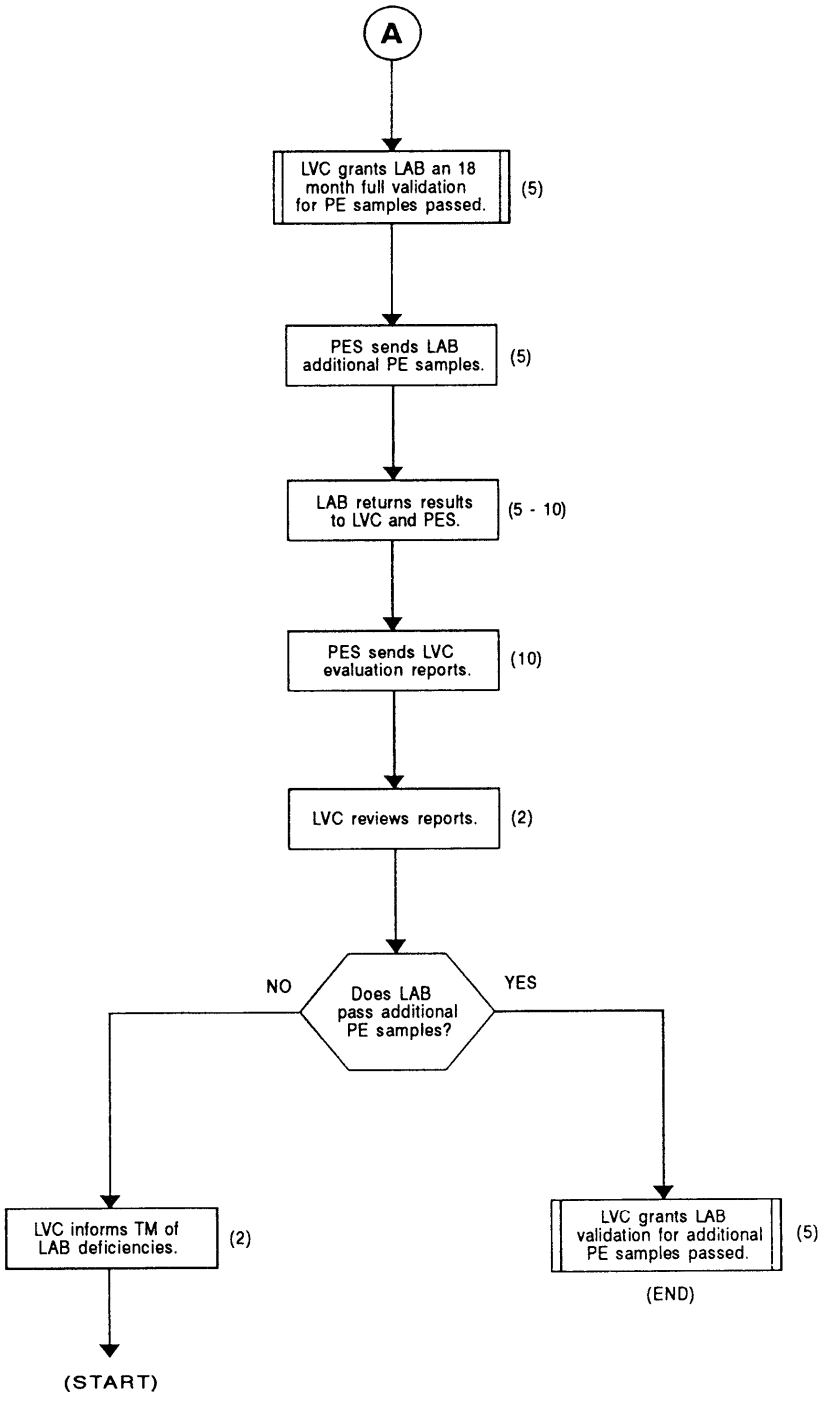

Figure 1-1. Flow Diagram of Commercial Laboratory Validation Procedures (continued)

Details on the responsibilities of all involved parties are addressed below.

a. HQUSACE:

(1) Actively performs oversight for the USACE HTRW laboratory validation program.

(2) Administers approval authority for the policies and procedures of the USACE HTRW laboratory validation program.

b. The Committee, HTRW MCX:

(1) Is responsible for all aspects of the USACE HTRW laboratory validation program including planning, programming, execution, budget, and management.

(2) Coordinates laboratory validation activities and provides liaison with various government agencies and private sector parties on laboratory validation issues. Ensures all laboratory evaluations and/or validations are successfully completed in a timely manner.

(3) Identifies the PE samples and analytical methods required for each laboratory validation. Assures that PE sample suppliers are provided with proper information to prepare and ship PE samples.

(4) Monitors the performance of PE sample suppliers through review of their most recent analytical results of any proficiency testing programs and all QA/QC data associated with the verification of PE samples on a quarterly basis. Also conducts on-site audits of PE sample suppliers on a regular basis.

(5) Reviews the qualification documents of commercial laboratories, evaluates PE sample results, and conducts or delegates on-site laboratory inspections.

(6) Trains USACE personnel to perform on-site laboratory inspections. Monitors the inspector's performance to ensure that consistent inspection approach and results of high quality are carried out within the USACE HTRW laboratory validation program.

(7) Decides the pass/fail status for each step of the laboratory validation process, additional work required for completion of laboratory validation, or the appropriate time to terminate a laboratory validation process or to revoke an active validation status.

(8) Prepares and distributes laboratory inspection and evaluation reports.

(9) Establishes and maintains a performance database for PE sample results from commercial laboratories. Statistically evaluates PE sample results to adjust or update the acceptance limits for PE sample analysis.

(10) Provides technical assistance to USACE Technical Managers/Contracting Officer Representatives (TM/CORs) to resolve problematic issues on laboratory validation and performance.

(11) Upon request, provides technical assistance to USACE TM/CORs in selection of contract laboratories prior to nomination for validation to support USACE HTRW response activities.

(12) Provides liaison with various government agencies and private sector parties on national laboratory "accreditation" programs. Revises the USACE HTRW laboratory validation program as needed to meet Federal and/or State regulatory requirements.

c. PE Sample Suppliers (including Waterways Experiment Station and Missouri River Division Laboratory):

(1) Prepare or purchase PE samples of high quality. Verify the PE samples prior to use. Maintain proper in-house documentation on PE sample preparation and verification per the U.S. Environmental Protection Agency (USEPA) and the USACE guidance. Arrange for multiple laboratory analyses of PE samples and statistically evaluate PE sample results to establish initial acceptance limits.

(2) Supply PE samples to candidate laboratories with overnight express delivery services. Ensure all PE samples are packed and shipped according to the USEPA, USACE, and the Department of Transportation (DOT) regulations and guidelines. Maintain a full chain-of-custody for each shipment of PE samples. Generate and send a sample-specific instruction letter for PE sample analysis with each PE sample shipment. Notify the Committee of any problems with PE sample preparation, verification, and shipment immediately.

(3) Provide technical assistance in resolving problems with PE sample analysis to the Committee and commercial laboratories. Keep the Committee informed of any major problems or issues on PE sample analysis.

(4) Evaluate PE sample results based on statistically established confidence limits for precision and accuracy.

Prepare and send written evaluation reports on PE sample results to the Committee within the required time frame. Provide the Committee with verbal reports on PE sample results, if a quick answer is needed.

(5) Ensure the availability and readiness of multiple sets of PE samples of different constituents and/or concentrations. Avoid sending same PE samples to same laboratory twice, including affiliated laboratories belonging to same parent corporation when possible.

(6) Actively participate in proficiency testing programs of State, Federal, and/or private firms. Provide the Committee with most recent proficiency testing results on a quarterly basis.

D. USACE TM/CORs:

(1) Submit a fully completed format of “Request for Evaluation of Commercial Laboratory” or an equivalent for each laboratory-project case to the Committee in a timely manner.

(2) Inform the Committee of any major changes in project requirements related to chemical analyses in a timely manner.

(3) Notify the Committee immediately to terminate validation efforts if a commercial laboratory undergoing the validation process is replaced by another commercial laboratory.

(4) Provide funding, if appropriate, for laboratory validation.

(5) Inform the Committee of any performance problems with sample analysis.

e. Prime Contractors (including Architect Engineering Firms, Construction Contractors, and Government Agencies):

(1) Select a subcontract laboratory and notify the USACE TM/COR early.

(2) Provide a subcontract laboratory a copy of the final Chemical Data Acquisition Plan (CDAP) for information prior to laboratory inspection. If a CDAP is not available prior to the inspection, as a minimum, provide a copy of the Scope of Services.

f. Analytical Chemistry Laboratories (including Commercial and Government Laboratories):

(1) Respond to the Committee's requirements within the required time frame.

(2) Follow instructions to analyze and report PE sample results.

(3) Inform the Committee immediately of any major changes on the laboratory's facility, instruments, or key technical staff during the laboratory's 18-month validation period.

1-6. Expenses and Funding.

In general, "billable" items related to specific laboratory validations include: travel and per diem for on-site inspection plus time and labor spent on review of documents, inspection of laboratory, and preparation of inspection report and on preparation, testing, and shipment of PE samples. Depending on the program, customer billable items are funded on a yearly program basis or project specifically. Mixed funding for a particular validation is used if appropriate. Verbal communication with the USACE TM/COR will cover the topic of funding for a particular request. For projects under programs or missions without yearly program funds available at the HTRW MCX, the USACE TM/CORs who request the validation shall be responsible for the expense of laboratory validation that is approximately $2,500 per laboratory validated. The cost of laboratory validation may be adjusted as needed, based on updated expenses.

1-7. Effective Date and Amendments.

a. This manual is effective upon approval by the HQUSACE and shall remain in effect until superseded or terminated.

b. These procedures may be modified, revised, or amended upon approval by the HQUSACE.

c. This manual and any future revisions or amendments shall be distributed by the HQUSACE.